906 KAR 1:110. Critical access hospital services.

RELATES TO: KRS 205.639, 211.842 -211.852, 216.378, 216.379, 216.380, 216B.010, 216B.015, 216B.040, 216B.042, 216B.045-216B.055, 216B.075, 216B.105, 216B.115 -216B.131, 311, 315, 333, 42 C.F.R. 485.601-42 C.F.R. 485.641

STATUTORY AUTHORITY: KRS 216.380(14), 216B.040(3)(a), 216B.042(1)(a), (c), 42 U.S.C. 1395i-4

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216.380(14) requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary to implement a program for licensure of critical access hospitals. This administrative regulation establishes quality of care and licensure standards for critical access hospitals.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

(2) "Licensee" means the entity that has been issued and holds a valid critical access hospital license from the Cabinet for Health and Family Services.

Section 2. Requirements for Critical Access Status. (1) An applicant for initial licensure of a critical access hospital shall provide documentation to the cabinet verifying that:

- (a) The requirements of KRS 216.380(3) or (4) have been met;
- (b) The hospital qualifies for state designation under 42 U.S.C. Section 1395i-4(c)(2); and
- (c) The requirements of this administrative regulation have been met.
- (2) A critical access hospital that was certified by the secretary of the cabinet as a necessary provider of services prior to January 1, 2006 may be relicensed as a critical access hospital, provided the requirements of this administrative regulation are met.
- (3) If an application for initial licensure of a critical access hospital is denied by the cabinet, the applicant shall be entitled to an administrative hearing pursuant to KRS Chapter 13B. Licensure hearings shall follow the procedures in 900 KAR 6:040.

Section 3. Administration and Operation. (1) The licensee shall be legally responsible for the operation of the critical access hospital and for compliance with federal, state, and local law pertaining to the operation of the critical access hospital.

- (2) A critical access hospital shall be under the medical direction of a physician licensed to practice medicine in Kentucky.
 - (3) The licensee shall:
 - (a) Establish written policies and lines of authority; and
- (b) Designate the person principally responsible for the daily operation of the critical access hospital.
- (4) The licensee shall develop patient care policies with the advice of a group of professional persons, as identified by the licensee.
 - (a) The group of professional persons shall include:
 - 1. One (1) or more physicians licensed in the Commonwealth of Kentucky; and
 - 2. One (1) or more persons who are not members of the staff.
 - (b) The patient care policies shall include:
- 1. A description of services that the critical access hospital shall provide directly or through contractual agreement;
 - 2. A written program narrative describing in detail the:
 - a. Services to be offered;
 - b. Methods and protocols for service delivery;
 - c. Qualifications of personnel to be involved in the delivery of services; and

- d. Outcomes expected to be attained through the delivery of specified services;
- 3. Guidelines for medical case management of health problems which include:
- a. Criteria for determining if a case requires medical consultation;
- b. Patient referral procedures; and
- c. Maintenance of health records;
- 4. Procedures for the proper storage, handling and administration of drugs and biologicals; and
- 5. Procedures establishing annual review and evaluation of services provided.
- (5) A critical access hospital shall establish written policies regarding patient rights and responsibilities. The policies shall assure that each patient is:
 - (a) Informed of:
 - 1. Patient rights;
 - 2. Rules and regulations governing patient conduct and responsibilities; and
 - 3. The procedure for handling a patient grievance;
- (b) Informed of services available and related charges, including charges not covered by Medicare, Medicaid, or other third-party payor;
 - (c) Informed of the:
- 1. Medical condition, unless medically contraindicated as documented in the patient's medical record:
 - 2. Right to participate in planning his or her medical treatment; and
 - 3. Right to refuse to participate in experimental research;
 - (d) Assisted in understanding his or her patient rights;
- (e) Provided confidential treatment of his or her records and given the opportunity to approve or refuse their release to an individual not involved in his or her care, except as required by Kentucky law or third-party payment contract;
- (f) Treated with consideration, respect, and recognition of the patient's dignity and individuality, including privacy in treatment and care of personal health needs; and
- (g) Informed of the procedure for filing a grievance or a recommendation to change a policy or service. The policy shall establish a time frame within which critical access hospital personnel shall determine what corrective action to take.
 - (6) Personnel.
 - (a) Staffing shall be in accordance with KRS 216.380(9).
 - (b) A physician shall:
 - 1. Be responsible for all medical aspects of the critical access hospital;
 - 2. Provide direct medical services in accordance with KRS Chapter 311;
- 3. Be present to provide medical direction, supervision, and consultation to the staff at least once in every two (2) week period, unless no patient has been treated since the last visit;
- 4. Participate with other medical personnel in developing, executing, and periodically reviewing written policies and services;
 - 5. Review and sign patient records during the site visit; and
- 6. Provide medical orders and medical care services to patients in accordance with the critical access hospital protocols.
- (c) A registered nurse or licensed practical nurse shall be on duty if a patient has been admitted for overnight stay.
- (7) The critical access hospital shall have transfer and linkage contracts that meet the requirements of KRS 216.380(11) and (12).
 - (8) Medical records.
- (a) A critical access hospital shall maintain medical records. A medical record shall contain at least the following:
 - 1. The names of the patient's immediate family members;

- 2. Medical and social history, including data obtainable from other providers;
- 3. Description of each medical visit or contact, including:
- a. Condition or reason necessitating visit or contact;
- b. Assessment;
- c. Diagnosis;
- d. Services provided;
- e. Medications and treatments prescribed; and
- f. Disposition made;
- 4. Reports of laboratory, x-ray, and other test findings; and
- 5. Documentation of referrals made, including:
- a. Reason for referral;
- b. To whom patient was referred; and
- c. Information obtained from referral source.
- (b) Confidentiality of individual patient records shall be maintained at all times.
- (c) Transfer of records. The critical access hospital shall establish systematic procedures to assist in continuity of care if the patient moves to another source of care, and shall, upon proper release, transfer medical records or an abstract upon request.
- (d) Retention of records. After a patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for five (5) years or, if the patient is a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.
- (9) Utilization review and medical audit. In order to determine the appropriateness of services delivered, there shall be a written plan for utilization review which specifies the frequency of reviews and composition of the body conducting the review.
 - (10) Quality assessment and performance improvement program.
- (a) A critical access hospital shall have a program, in accordance with KRS 216.380(10), to ensure continuous and effective mechanisms for:
 - 1. Review and evaluation of patient care; and
 - 2. Corrective action.
 - (b) The program shall be approved by the licensee.
 - (c) The program shall:
 - 1. Establish responsibility for monitoring and evaluation of services;
 - 2. Delineate the scope of care;
 - 3. Identify specific aspects of care to be provided;
 - 4. Establish and document clinical criteria used to monitor care and services;
- 5. Systematically evaluate the standard of care to identify problems and recommend corrective action or alternatives to improve the standard of care;
 - 6. Establish criteria to assess the effectiveness of corrective action taken to improve care; and
- 7. Require documentation of improvements in the standard of care, subsequent to corrective action taken.
- (11) Contracted services. The critical access hospital shall assure that a service provided under contract is properly licensed or certified in accordance with applicable local, state, and federal regulations and statutes.
- Section 4. Provision of Services. (1) A critical access hospital shall provide the services in accordance with KRS 216.380(5).
- (2)(a) A critical access hospital shall provide, either directly or through contract, basic laboratory services essential to the immediate diagnosis and treatment of the patient.
- (b) If the critical access hospital provides laboratory services directly, the service shall be in compliance with 902 KAR 20:016, Section 4(4).

- (c) If the critical access hospital contracts for laboratory services, the laboratory it contracts with shall be in compliance with KRS Chapter 333.
 - (d) The following services shall be provided:
- 1. Chemical examination of urine, including ketone measurement, by stick or tablet method, or both;
 - 2. Microscopic examination of urine sediment;
 - 3. Hemoglobin or hematocrit;
 - 4. Blood sugar;
 - 5. Examination of stool specimens for occult blood;
 - 6. Pregnancy tests; and
 - 7. Primary culturing for transmittal to a hospital laboratory or licensed laboratory.
- (3) A critical access hospital shall provide medical emergency procedures as a first response to common life-threatening injuries and acute illness, and shall have available the drugs and biologicals commonly used in life-saving procedures, such as analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.
- (a) Examination services shall be provided by the critical access hospital in accordance with 902 KAR 20:012.
- (b) There shall be a physician, nurse practitioner, or physician assistant with training or experience in emergency care on-call and immediately available by telephone or radio contact, and available on site within thirty (30) minutes on a twenty-four (24) hour per-day basis.
- (c) A registered nurse shall be on duty at the hospital to provide immediate emergency care on a twenty-four (24) hour per day basis.
- (4) In accordance with KRS 216.380(5)(b), a critical access hospital shall provide, either directly or through contract, basic pharmacy services essential to the treatment of the patient.
- (a) If the critical access hospital provides pharmacy services directly, it shall be in compliance with 902 KAR 20:016, Section 4(5).
- (b) If the critical access hospital contracts for pharmacy services, the pharmacy it contracts with shall be in compliance with KRS Chapter 315.
- (5) In accordance with KRS 216.380(5)(b), a critical access hospital shall provide, either directly or through contract, basic radiology services essential to the immediate diagnosis and treatment of the patient.
- (a) If the critical access hospital provides radiology services directly, it shall be in compliance with 902 KAR 20:016, Section 4(6).
- (b) If the critical access hospital contracts for radiology services, the radiology service it contracts with shall have a current license or registration pursuant to KRS 211.842 to 211.852.
- (6) Pursuant to KRS 216.380(5)(b), dietary services shall be provided either directly or by contract, in accordance with 902 KAR 20:016, Section 4(3), if a patient is admitted to the critical access hospital and remains for more than twelve (12) hours.
- (7) A critical access hospital that has established a psychiatric unit in accordance with KRS 216.380(7)(a), shall be in compliance with 902 KAR 20:180.
- (8) A critical access hospital that has established a rehabilitation unit in accordance with KRS 216.380(7)(b), shall be in compliance with 902 KAR 20:240.

Section 5. Physical and Sanitary Environment. A critical access hospital shall comply with the provisions of 902 KAR 20:016, Section 3(10).

Section 6. Facility Requirements. A critical access hospital shall comply with the requirements of 902 KAR 20:009 related to the services offered. (18 Ky.R. 3562; Am. 19 Ky.R. 424; eff. 8-28-92; 25 Ky.R. 2979; 26 Ky.R. 398; eff. 8-16-99; 27 Ky.R. 1624; 2173; eff. 2-1-2001; 32 Ky.R. 2380;